January 08, 2019

Via Email: orapharm1recalls@fda.hhs.gov

LCDR Dellarese Herbert
Div. of Pharmaceutical Quality Operations
US Food and Drug Administration
Philadelphia District Office
900 US Customhouse, Suite 904
200 Chestnut Street
Philadelphia, PA 19106

Subject: Voluntary Recall of Fluocinolone Acetonide Topical Solution, USP 0.01%, NDC 0591-2990-60

Recall #: D-0909-2018

Lot Number	Exp. Date	Strength	Bottle Size
1164898	10/2018	0.01%	60 mL
1164904	11/2018	0.01%	60 mL
1164909	11/2018	0.01%	60 mL
1211396	07/2019	0.01%	60 mL
1230808	01/2020	0.01%	60 mL
1231127	01/2020	0.01%	60 mL

Dear LCDR Herbert,

As of January 08, 2018, Teva Pharmaceuticals USA, Inc. is formally requesting the closure of the above referenced voluntary recall which was initiated July 05, 2018. We have evaluated our recall for termination and determined that all possible customer responses have been received. We have determined that it is reasonable to assume that the recalled product has been satisfactorily removed, and all returned product has been destroyed. As such, the recall is effective in accordance with the criteria set forth in 21 CFR 7.55 paragraph (a). Corrective/Preventive Action(s) was (were) implemented to address root cause. See attached Final Field Alert report attached.

Should you require additional information or have any questions concerning this report, please contact me at 973-658-1839 or at constance.truemper@actavis.com.

Please address Recall Closure to:

Most responsible individual of recalling firm:
Carlo De Notaristefani
Executive Vice President, Global Operations, Global Operations
Teva Pharmaceuticals USA, Inc.
Morris Corporate Center III
400 Interpace Parkway
Parsippany, NJ 07054

Copy to:
Connie T. Truemper
Manger, Regulatory Compliance
Teva Pharmaceuticals USA, Inc.
Morris Corporate Center III
400 Interpace Parkway
constance.truemper@actavis.com

Sincerely,

01/08/2019

CONNIE T TRUEMPER, Manager, Regulatory Compliance, Teva Pharmaceuticals USA, Inc.

Copy to: David Bonilla, Associate Director, Quality & Compliance, Teva Pharmaceuticals USA, Inc.

/Enclosures:
Recall Status Summary
Certificate (s) of Destruction
Final Field Alert

teva

Oct 01 09/12

Fluocinolone Acetonide Topical Solution, USP 0.01%, NDC 0591-2990-60
Recall Status through January 7, 2019

1.	Number of Direct Consignees notified of the recall by Federal Express mail	57
2.	Number of Direct Consignees responding:	
	Number with Stock to return	29
	Number with No stock to return	13
3.	Number of Direct Consignees not responding (after conducting effectiveness checks)	15
4.	Amount of returned product from all Direct and Indirect consignees (Bottles) [1]	6,243
	Amount of returned product from all Direct and Indirect consignees destroyed (Bottles) [1]	6,233
5.	Amount of undistributed product remaining in Teva warehouse at time of recall. (Bottles)	11,240
	Amount of undistributed product remaining in Teva warehouse at time of recall destroyed. (Bottles)	11,240
6.	Total Amount of product destroyed (Bottles)	17,473
7.	Effectiveness Checks [2]	
	Number contacted	24
	Received original recall notice	24
	Stock to return	9
	No stock to return	15

Notes:

1. The remaining merchandise and any subsequent returned goods will be destroyed via incineration in subsequent on-going destruction events.
2. 100% of all direct consignees who did not respond via the Stock Response Form (SRF) were contacted for effectiveness checks. As of 11/29/2018, there were 34 that had not responded. Of these consignees, 10 were unreachable; however, FedEx proof of delivery is shown for all except 1 consignee (McKesson, Delran, NJ).

Teva Pharmaceuticals
1090 Horsham Road, North Wales, PA 19454, USA | T: 215.591.3000 | www.tevausa.com